

## What is claimed

1. A method of conducting clinical drug trials by pharmacogenetic stratification of a  
5 patient population, comprising the steps of:
  - (a) Conducting a first clinical drug trial on a patient population, such that said drug trial identifies an association between a phenotype and a genotype;
  - (b) Separating said patient population in said clinical drug trial into sub-populations of responders and non-responders;
  - 10 (c) Conducting a subsequent clinical drug trial on a non-responder patient population such that said subsequent drug trial identifies a subsequent association between a phenotype and a genotype;
  - (d) Separating the patient population of step (c) into subsequent responder and subsequent non-responder patient populations; and
  - 15 (e) Repeating steps (c) and (d) through as many iterations as desired.
2. A method of conducting clinical drug trials by pharmacogenetic stratification of a  
patient population, comprising the steps of:
  - (a) Conducting a first clinical drug trial on a patient population, such that said  
20 drug trial identifies an association between a phenotype and a genotype, where said phenotype is an observed response or lack thereof to a drug being studied in said drug trial;
  - (b) Separating said patient population in said clinical drug trial into sub-populations of responders and non-responders;
  - 25 (c) Conducting a subsequent clinical drug trial on a non-responder patient population such that said subsequent drug trial identifies a subsequent association between a phenotype and genotype, where said phenotype is an observed response or lack thereof to a drug being studied ins said subsequent drug trial;
  - 30 (d) Separating the patient population of step (c) into subsequent responder and subsequent non-responder patient populations; and



- (e) Repeating steps (c) and (d) through as many iterations as desired.
3. A method of conducting clinical drug trials by pharmacogenetic stratification of a patient population, comprising the steps of:
- 5 (a) Conducting a first clinical drug trial on a patient population, such that said drug trial identifies an association between a phenotype and a genotype, where said phenotype is an observed response or lack thereof to a drug being studied in said drug trial;
- 10 (b) Separating said patient population in said clinical drug trial into sub-populations of responders and non-responders;
- (c) Identifying a target for drug intervention for non-responders;
- (d) Screening candidate drug compounds against said target until a candidate drug is found;
- 15 (e) Conducting a subsequent clinical drug trial on a non-responder patient population such that said subsequent drug trial identifies a subsequent association between a phenotype and genotype;
- (f) Separating the patient population of step (e) into subsequent responder and subsequent non-responder patient populations; and
- (g) Repeating steps (c) and (f) through as many iterations as desired.
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4. A method of conducting clinical drug trials by pharmacogenetic stratification of a patient population, comprising the steps of:
- (a) Conducting a first clinical drug trial on a patient population, such that said drug trial identifies an association between a phenotype and a genotype,
- 25 (b) Separating said patient population in said clinical drug trial into sub-populations of responders and non-responders;
- (c ) Conducting a subsequent clinical drug trial on a non-responder patient population such that said subsequent drug trial identifies a subsequent association between a phenotype and a genotype;
- 30 (d) Separating the patient population of step (c) into subsequent responder and subsequent non-responder patient populations; and



- (e) Repeating steps (c ) and (d) through as many iterations as desired.
5. A method of designing novel drug therapies by pharmacogenetic stratification of a patient population, comprising the steps of:
- 5 (a) Conducting a first clinical drug trial on a patient population, such that said drug trial identifies an association between a phenotype and a genotype;
- (b) Separating said patient population in said clinical drug trial into sub-populations of responders and non-responders;
- 10 (c) Conducting a subsequent clinical drug trial on a non-responder patient population such that said subsequent drug trial identifies a subsequent association between a phenotype and a genotype;
- (d) Separating the patient population of step (c) into subsequent responder and subsequent non-responder patient populations; and
- (e) Repeating steps (c)and (d) through as many iterations as desired.
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6. A method of developing discrete drugs for different patients who have clinically similar disease phenotypes, but who have discrete genotypes, by pharmacogenetic stratification of a patient population, comprising the steps of:
- 20 (a) Conducting a first clinical drug trial on a patient population, such that said drug trial identifies an association between a phenotype and a genotype;
- (b) Separating said patient population in said clinical drug trial into sub-populations of responders and non-responders;
- (c) Conducting a subsequent clinical drug trial on a non-responder patient population such that said subsequent drug trial identifies a subsequent association
- 25 between a phenotype and a genotype;
- (d) Separating the patient population of step (c) into subsequent responder and subsequent non-responder patient populations; and
- (e) Repeating steps (c)and (d) through as many iterations as desired
- 30 7. The method of claim 1, where said phenotype is a diagnosis of Alzheimer's Disease.



8. The method of claim 1, where said phenotype is a diagnosis of irritable bowel syndrome.
9. The method of claim 1, where said phenotype is a diagnosis of migraine headache.
- 5 10. The method of claim 1, where said phenotype is a diagnosis of psoriasis.
11. The method of claim 1 where said phenotype is a diagnosis of non-insulin dependant diabetes mellitus.
- 10 12. The method of claim 1 where said phenotype is a diagnosis of asthma.
13. The method claim 1 where said phenotype is a diagnosis of chronic obstructive pulmonary disease.
- 15 14. The method of claim 1, where said phenotype is a diagnosis of bipolar disorder.
15. The method of claim 1, where said phenotype is a diagnosis of depression.
- 20 16. The method of claim 1, where said phenotype is a diagnosis of one or more forms of epilepsy.
17. The method as claimed in claim 1, in which the population of a first or subsequent clinical drug trial can alternatively be separated into responder, non-responder and partial-responder populations.
- 25 18. The method as claimed in claim 1, and further wherein any nucleotide sequence data, amino acid sequence data, protein-protein interaction data, clinical diagnosis data or statistics data generated by the above procedure is stored in electronically readable media and is communicated via telecommunication means between at least two electronic computing devices.
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